SEP - 6 2001

K011818

Nicolet
BIOMEDICAL

Summary of Safety and Effectiveness

Company Name: Nicolet Biomedical Incorporated
5225 Verona Road
Madison, WI 53711

Contact: Glen Hermanson, Manager of Standards and Compliance
Phone: 608 441-2065
Fax: 608 441-2007

Summary Date: June 7, 2001

Trade Name: Sterile EMG Electrodes

Common Name: EMG Electrodes

Classification Name: 21 CFR 890.1385, EMG Needle Electrode

Predicate Device(s):

510(k) Number: K850107
Manufacture: Nicolet Biomedical Incorporated
Trade Name: Concentric EMG Electrodes (non-sterile)
Product Code: IKT
Classification: 21 890.1385, Diagnostic Electromyograph Needle Electrode

510(k) Number: K912282, K924521, K955335, K982950
Manufacture: Chalgren, Incorporated
Trade Name: Disposable Monopolar EMG Electrode, Disposable Concentric Needle Electrode, Disposable Hypodermic Monopolar Needle, Fine Wire Electrode (Hook Wire)
Product Code: IKT
Classification: 21 890.1385, Diagnostic Electromyograph Needle Electrode

510(k) Number: K912783
Manufacture: Class A Incorporated
Trade Name: Disposable Monopolar Needle Electrode
Product Code: GXZ
Classification: 21 882.1350, Needle Electrode

Packaging and sterilization of the EMG electrodes is equivalent to the Subdermal Needle Electrodes, described in the following Nicolet Biomedical 510(k):

510(k) Number: K010019
Manufacture: Nicolet Biomedical
Trade Name: Subdermal Needle Electrodes

1.0 Description of Electrodes

EMG electrodes are applied in the study of biopotentials such as electromyograph (EMG), nerve conduction and stimulation/response. Electrodes are invasive as they are placed in contact with nerve or muscle tissue.

The electrodes consist of a needle with a connector/lead wire attached. The connector/lead wires terminate in a safety connector that cannot be connected to an AC power outlet.

The electrodes provide the patient contact device. The electrodes connect to the user's recording, monitoring and stimulation/response equipment. The electrodes are used under the supervision of a physician.

2.0 Intended Use of Electrodes

EMG electrodes are intended for use with recording, monitoring and stimulation/recording equipment for the stimulation/recording of biopotential signals including electromyograph (EMG) and nerve potential signals.

3.0 Technological Characteristics

The EMG electrodes consist of a needle with a connector or lead wire attached. The connector or lead wires terminate in a safety connector that cannot be connected to an AC power outlet. The EMG Electrodes are provided sterile and for single patient use.

4.0 Conclusions

The characteristics of the EMG Electrodes are substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2001

Nicolet Biomedical, Inc.
c/o Mr. Gary Syring
Quality and Regulatory Associates, LLC
800 Levanger Lane
Stoughton, Wisconsin 53589

Re: K011818
Trade/Device Name: Sterile EMG Electrodes
Regulation Number: 890.1385, 882.1350
Regulation Name: Diagnostic electromyograph needle electrode
Needle electrode
Regulatory Class: II
Product Code: IKT, GXZ
Dated: June 8, 2001
Received: June 11, 2001

Dear Mr. Syring:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Walter, M.D.

For Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011818

Device Name: Sterile EMG Electrodes

Indications For Use:

Concentric, Monopolar, Hook Wire and Hypodermic EMG Electrodes are intended for use with recording, monitoring and stimulation/recording equipment for the stimulation/recording of biopotential signals including electromyograph (EMG) and nerve potential signals.

(PLEASE: DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011818

(Optional Format 3-10-98)